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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/661,361	Confirmation No. 6762
Applicant	:	David A. Mackiewicz, et al.	
Filed	:	September 12, 2003	
Art Unit	:	3731	
Examiner	:	Elizabeth Houston	
Title	:	RADIOPAQUE MARKERS FOR MEDICAL DEVICES	
Docket No.:	:	ENDOS 64949 (G4164US01)	
Customer No.	:	68,919	April 12, 2010

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**APPEAL BRIEF**

Dear Sir:

This Appeal Brief is being filed pursuant to the Notice of Appeal filed on January 11, 2010 from the Final Office Action dated September 10, 2009. This Appeal Brief is being filed within one (1) month of the Notice of Panel Decision dated March 11, 2010.

**INTRODUCTION**

The presently claimed invention is directed to an implantable medical device, such as a stent, for use or implantation in the body or a body lumen. The implanted medical device includes a structural body made from a superelastic material, such as a nickel-titanium alloy, which attains a certain level of

radiopacity. The structural body includes one or more marker holders formed with the structural body. Each marker holder is designed to hold a radiopaque marker which has a level of radiopacity greater than the superelastic material. Each marker holder includes a pair of projecting fingers connected together at a notched region to cooperatively create a V-shaped opening. This V-shaped opening, in turn, is adapted to receive a portion of the radiopaque marker having a V-shape as well. The V-shaped opening formed by the pair of projecting fingers creates a mounting region that allows the projecting fingers to move outwardly, if necessary, in order to receive the V-shaped portion of the radiopaque marker. In this regard, such a mounting structure allows the marker holder to easily compensate for derivations caused by an imprecise fit between the radiopaque marker and the pair of projecting fingers. Each projecting finger of the marker holder has a substantially linearly extending contact edge formed thereon. Each radiopaque marker includes a pair of substantially linearly extending contact edges which make contact with the contact edges formed on the projecting fingers. A melt or heat weld could be used at the abutment of the radiopaque marker with the projecting fingers to securely affix the components together.

The present application, U.S. Serial No. 10/661,361 was filed on September 12, 2003.

## I. **REAL PARTY IN INTEREST**

The real party in interest in this appeal is ABBOTT VASCULAR SOLUTION INC., 3200 Lakeside Drive, Santa Clara, CA 95054, which is a division of Abbott Laboratories, 100 Abbott Park Road, Abbott Park, Illinois 60664-3500. This application was originally assigned by the inventors, DAVID A. MACKIEWICZ, KEIF FITZGERALD and BORIS ANUKHIN to GUIDANT ENDOVASCULAR SOLUTIONS, by Assignment executed on February 16, 2004,

February 18, 2004 and February 20, 2004, which was recorded by the U.S. Patent Office on March 22, 2004 beginning at Reel 015119, Frame 0430. ABBOTT VASCULAR SOLUTIONS INC. is the owner of this application as is evidenced by the Assignment dated February 16, 2007 which was recorded by the U.S. Patent Office on November 19, 2008 at Reel 021858, Frame 0161.

## **II. RELATED APPEALS AND INTERFERENCES**

With respect to other appeals or interferences that will directly effect, or be directly effected by, or have a bearing on the Board's decision on this appeal, it is to be noted that is believed there are no such appeals or interferences known to the Appellant.

## **III. STATUS OF CLAIMS**

### **A. Total Number of Claims in the Application**

The claims in the application are: Claims 1-4, 6-15, 17, 18, 21, 32, 42-52. Claims 5, 16, 19, 20, 22-31 and 33-41 have been canceled without prejudice.

### **B. Status of All Claims on Appeal**

Claims 1-4, 6, 7, 32, 42, 51 and 52 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,741,327 to Frantzen (the "Frantzen patent") in view of DE Patent 19728337 to Ehrfeld (the "Ehrfeld patent").

Claims 8-15, 17, 18, 21 and 43-50 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Frantzen patent in view of the Ehrfeld patent and in further view of U.S. Patent No. 6,503,271 to Duerig et al. (the "Duerig patent").

### **C. Claims on Appeals**

The claims on appeal are each of pending claims 1-4, 6-1517, 18, 21, 32, 42-52. A copy of the claims being appealed is appended as Exhibit 1.

#### **IV. STATUS OF AMENDMENTS**

On September 10, 2009, the Examiner issued a final Office Action maintaining the §103 rejections of the pending claims. Appellant filed a Pre-Appeal Brief Request For Review on January 11, 2010. A Notice of Panel Decision issued on March 11, 2010 stating that there is still at least one issue for appeal. The finally rejected claims attached to this brief are the subject of this appeal.

#### **V. SUMMARY OF THE CLAIMED SUBJECT MATTER**

##### **Independent Claim 1**

Independent claim 1 is supported in the drawings and specification as follows:

1. (Previously Presented) An implantable medical device having enhanced radiopacity, comprising:

a structural body (page 8, lines 2-15, FIG. 1, # **10**) formed from a biocompatible material having a certain level of radiopacity, the structural body including at least one marker holder integrally formed therein (page 9, lines 1-6, FIGS. 1, 2 and 3, # **22**); and

a radiopaque marker (page 8, lines 17-24, FIGS. 1, 2 and 3, # **20** ) made from a material having a level of radiopacity greater than the level of radiopacity of the biocompatible material from which the structural body is formed, the radiopaque marker being attachable within the marker holder, wherein the marker holder includes a pair of longitudinally projecting fingers (page 9, lines 9-10, FIGS. 2 and 3, # **26**) which define a substantially V-shaped opening (page 9, lines 10-22, FIGS. 2 and 3, # **30**), wherein each projecting finger has a substantially linearly extending contact edge (FIGS. 2 and 3, along # **30**) formed

thereon and the radiopaque marker includes a substantially V-shaped mounting region (page 9, lines 10-22, FIGS. 2 and 3, # **32**) which fits within the V-shaped opening defined by the pair of longitudinally projecting fingers, the radiopaque marker having a pair of substantially linearly extending contact edges (FIGS. 2 and 3, along # **32**) formed thereon each of which contacts a contact edge of the projecting fingers.

### **Independent Claim 8**

Independent claim 8 is supported in the drawings and specification as follows:

8. (Previously Presented) An implantable medical device having enhanced radiopacity, comprising:

a structural body (page 8, lines 2-15, FIG. 1, # **10**) formed from a superelastic alloy having a certain level of radiopacity, the structural body including at least one marker holder (page 9, lines 1-6, FIGS. 1, 2 and 3, # **22**); and

a radiopaque marker (page 8, lines 17-24, FIGS. 1, 2 and 3, # **20**) made from a nickel-titanium alloy including a ternary element which attains a level of radiopacity greater than the level of radiopacity of the superelastic alloy from which the structural body is formed, the radiopaque marker being attachable within the marker holder, wherein the marker holder includes a pair of projecting fingers (page 9, lines 9-10, FIGS. 2 and 3, # **26**) which define a substantially V-shaped opening (page 9, lines 10-22, FIGS. 2 and 3, # **30**) and each projecting finger has a substantially linearly extending contact edge (FIGS. 2 and 3, along # **30**) formed thereon, the radiopaque marker including a substantially V-shaped mounting region (page 9, lines 10-22, FIGS. 2 and 3, # **32**) that fits within the V-shaped opening defined by the projecting fingers, the mounting region of the marker

including a pair of substantially linearly extending contact edges (FIGS. 2 and 3, along # **32**), each of which comes in contact with a contact edge of a projecting finger, the projecting fingers applying a force on the V-shaped mounting region which holds the radiopaque marker on the marker holder.

### **Independent Claim 42**

Independent claim 42 is supported in the drawings and specification as follows:

42. (Previously Presented) An implantable medical device having enhanced radiopacity, comprising:

a structural body (page 8, lines 2-15, FIG. 1, # **10**) formed from a biocompatible material having a certain level of radiopacity, the structural body including at least one marker holder integrally formed therein (page 9, lines 1-6, FIGS. 1, 2 and 3, # **22**) ; and

a radiopaque marker (page 8, lines 17-24, FIGS. 1, 2 and 3, # **20** ) made from a material having a level of radiopacity greater than the level of radiopacity of the biocompatible material from which the structural body is formed, the radiopaque marker being attachable within the marker holder, wherein the marker holder includes a pair of projecting fingers (page 9, lines 9-10, FIGS. 2 and 3, # **26**) extending away from the structural body to form an opening having a first shape (page 9, lines 10-22, FIGS. 2 and 3, # **30**), each projecting finger having a substantially linearly extending contact edge (FIGS. 2 and 3, along # **30**), the radiopaque marker including a mounting region (page 9, lines 10-22, FIGS. 2 and 3, # **32**) having substantially the same shape as the first shape of the opening formed by the projecting fingers, the mounting region including substantially linearly extending side edges (FIGS. 2 and 3, along # **32**) adapted to contact the

projecting fingers to cause the fingers to move outwards to move the opening into a second, expanded shape in which the side edges of the mounting region contact the side edge formed on each projecting finger.

### **Independent Claim 43**

Independent claim 43 is supported in the drawings and specification as follows:

43. (Previously Presented) An implantable medical device having enhanced radiopacity, comprising:

a structural body (page 8, lines 2-15, FIG. 1, # **10**) formed from a nickel-titanium alloy, the structural body including a plurality of marker holders integrally formed therein (page 9, lines 1-6, FIGS. 1, 2 and 3, # **22**); and

a plurality of radiopaque markers (page 8, lines 17-24, FIGS. 1, 2 and 3, # **20**) made from a nickel-titanium-platinum alloy, each radiopaque marker being attachable within one of the marker holders, wherein each marker holder includes a pair of projecting fingers (page 9, lines 9-10, FIGS. 2 and 3, # **26**) extending away from the structural body to form an opening having a first shape (page 9, lines 10-22, FIGS. 2 and 3, # **30**), each projecting finger having a substantially linearly extending contact edge (FIGS. 2 and 3, along # **30**) formed thereon, and each radiopaque marker includes a mounting region (page 9, lines 10-22, FIGS. 2 and 3, # **32**) having substantially the same shape as the first shape of the opening formed by the projecting fingers, each mounting region including substantially linearly extending side edges(FIGS. 2 and 3, along # **32**) adapted to contact the contact edge formed on the projecting fingers of a marker holder to cause the projecting fingers to move outward to move the opening into a second, expanded shape.

## **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

The grounds for appeal are as follows:

### **GROUND I**

Whether claims 1-4, 6, 7, 32, 42, 51 and 52 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Frantzen patent (Exhibit 2) in view of the Ehrfeld patent (Exhibit 3).

### **GROUND II**

Whether claims 8-15, 17, 18, 21 and 43-50 were improperly rejected under 35 U.S.C. § 103(a) as being unpatentable over the Frantzen patent in view of the Ehrfeld patent and in further view of the Duerig patent (Exhibit 4).

## **VII. ARGUMENT**

### **GROUND I**

#### **A. Rejection of the Claims Based on the Frantzen and Ehrfeld Patents**

Claims 1-4, 6, 7, 32, 42, 51 and 52 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Frantzen patent in view of the Ehrfeld patent. Appellant notes that in the final Office Action, the Examiner acknowledges in paragraph 3 that the Frantzen patent fails to disclose the use of a marker holder having projecting fingers with a substantially linearly extending contact edge, the use of a V-shaped opening or that the radiopaque marker includes a V-shaped mounting area region with linearly extending contact edges. The Examiner relies on the Ehrfeld patent to disclose the shortcomings in the Frantzen patent. However, Appellant strongly disagrees with the Examiner's position for a number of reasons. Moreover, as Appellant will show, the Examiner rejects the claims without even addressing particular structural details found in each claim, namely, the recitations that each marker holder has a pair of projecting fingers and each

finger has a substantially linearly extending contact edge, along with the recitation that the mounting area of each radiopaque marker has a pair of linearly extending contact edges formed thereon which contacts a contact edge located on the projecting fingers.

First, Appellant submits that the Ehrfeld patent appears to be directed to **a mechanism for locking the struts forming the stent body** into an expanded configuration. The Ehrfeld mechanism has nothing to do with attaching separate components to a stent, no less attaching radiopaque markers to a stent. The Frantzen patent teaches the use of radiopaque markers at the ends of a stent in order to increase the overall radiopacity of the stent. The Frantzen patent does not disclose the use of a structure/mechanism for locking the stent body into an expanded position. Therefore, one skilled in the art, in viewing both the Frantzen patent and the Ehrfeld patent, would readily recognize that the locking mechanism disclosed in the Ehrfeld patent could possibly be incorporated into the stent disclosed in the Frantzen patent. This feature would allow the stent body disclosed in the Frantzen patent to be capable of being locked into an expanded position as well, which is the exact and straightforward teaching of the Ehrfeld patent. The Examiner's position that one skilled in the art would somehow **modify** the Ehrfeld locking mechanism to connect separately formed radiopaque markers to a stent goes well beyond the teachings of the Ehrfeld patent.

Appellant submits that the composite stent created from the combination of the Frantzen patent with the Ehrfeld patent would include both radiopaque markers located at the ends of the stent, as is disclosed and taught in the Frantzen patent, along with a locking mechanism for maintaining the stent in the expanded position, as is disclosed and taught in the Ehrfeld patent. In regard, this composite stent would enjoy the benefits of the features disclosed in both of these references. However, this composite stent formed from the Frantzen patent and the Ehrfeld

patent is not the structure recited in the pending claims. For this reason alone, the combination of the Frantzen patent with the Ehrfeld patent would not create the structure recited in the pending claims. It is submitted that the particular combinations of art relied on by the Examiner would not have achieved the innovative structure defined in the pending claims.

However, even assuming *arguendo* that one skilled in the art would incorporate the locking mechanism disclosed in the Ehrfeld patent into the stent of Frantzen for the purpose of providing a more secure fit, as suggested by the Examiner, it is noted that the Ehrfeld patent fails to disclose certain structural elements recited in the pending claims. The pending claims require each projecting finger to have **a substantially linearly extending contact edge** formed thereon and the radiopaque marker to include **a pair of substantially linearly extending contact edges** formed thereon each of which contacts a contact edge of the projecting fingers. The claim language is directed to the shape of the outermost edge of the fingers and the marker. While the Ehrfeld patent may disclose the use of two projecting fingers, the rejected claims require each projecting finger to have a substantially linearly extending contact edge formed thereon. Such a structure is clearly lacking in the Ehrfeld patent. The Examiner relies on the embodiment of FIG. 4a in the Ehrfeld patent to support this position. However, as is clear in FIG 4a, reproduced below, the contact edge 24a formed on the fingers 26a of the

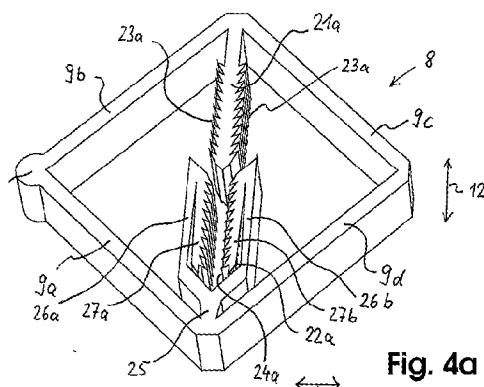


Fig. 4a

Ehrfeld device is anything but linearly extending. The contact edge 24a located on each finger of the Ehrfeld device is zigzag in shape and cannot be reasonably considered to be substantially linear in shape. In Appellant's Amendment filed prior to the final Office Action of September 10, 2009, it was made clear that the claimed structure was directed to the linear shape of the contact edge located on both the fingers and the markers. Appellant made it clear in that Amendment that the zigzag shape of contact edge 24a of the Ehrfeld device could not be reasonably considered "linearly extending."

The claims also require each radiopaque marker to have **a pair of substantially linearly extending contact fingers**. In the Ehrfeld patent, the contact edge 23a of the component 21a which engages the fingers 26a are similarly zigzag in shape in order to fit within the V-shaped openings formed on the contact face 24a of each finger 26a. Again, these components cannot be reasonably interpreted as being substantially linear in shape. It is noted that the Examiner's position regarding the Ehrfeld patent can be found at paragraphs 4 and 5 of the final Office Action. Appellant notes that the Examiner fails to even address where the substantially linear extending contact edges can be found in the Ehrfeld patent.

The Examiner also has identified the notches 22a and 24a formed on **each individual projecting finger** as the V-shaped opening. However, the claims do not call for the V-shaped opening to be formed on each individual projecting finger. Rather, it is the combination of the two spaced apart projecting fingers which define the V-shaped opening. As can be seen in FIG. 4a above, such a structure is clearly lacking in the Ehrfeld device.

For all of these reasons, it is clear that the Examiner has failed to establish a *prima facie* case of obviousness based on the combination of the Frantzen patent and the Ehrfeld patent.

## **GROUND II**

### **A. Rejection of the Claims Based on the Frantzen, Ehrfeld and Duerig Patents**

Claims 8-15, 17, 18, 21 and 43-50 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Frantzen patent in view of the Ehrfeld patent and in further view of the Duerig patent. All of these claims have been rejected on the basic combination of the Frantzen patent and the Ehrfeld patent. As addressed above, the combination of the Frantzen patent with the Ehrfeld patent would simply fail to create the basic structure now recited in all of the rejected claims. The Duerig patent has been cited merely to show the use of a particular alloy for manufacturing the marker. This secondary reference relied on the Examiner fails to address the shortcomings of the Frantzen/Ehrfeld combination in achieving the basic structure of the rejected claims. For this reason alone, the combination of references suggested by the Examiner would simply not produce the structure recited in the rejected claims.

**VIII. CLAIM APPENDIX**

See Exhibit 1.

**IX. EVIDENCE APPENDIX**

None.

**X. RELATED PROCEEDINGS APPENDIX**

NONE

## XI. CONCLUSION

Appellant respectfully requests that the obviousness rejections based on the combination of the Frantzen and Ehrfeld patents alone, or in further combination with the Duerig patent, be withdrawn. The combination of these references fails to create the basic structure recited in all of the pending claims.

The fee of \$540.00 for the filing of Appellant's Appeal Brief is being paid concurrently herewith. The Commissioner is hereby authorized, however, to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 06-2425.

Respectfully submitted,

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